This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

What is claimed is:

- 1. A method of turning a medical device, having a magnetically responsive element associated with its distal end, at an operating point within an operating region inside a patient's body from an initial direction to a desired final direction, through the movement of at least one external source magnet, the method comprising:
- moving the at least one external source magnet in such a way as to change the direction of the distal end of the magnetic medical device from the initial direction to the desired final direction without substantial deviation from the plane containing the initial direction and the desired final direction.
 - 2. The method according to claim 1 wherein the movement of the at least one source magnet comprises translations and rotations.
 - 3. The method according to claim 2 wherein the movement of the at least one source magnet includes translation in one direction and rotations in two directions.
 - 4. The method according to claim 1 wherein the at least one source magnet is moved in such a way as to maintain a substantially constant magnetic field strength at the operating point.
 - 5. The method according to claim 1 wherein the step of moving the at least one external source magnet includes moving the at least one external source magnet to cause the distal end of the magnetic medical device to successively align with a plurality of intermediate directions in a plane containing the initial direction and the desired final direction.
 - 6. The method according to claim 5 wherein the movement of the at least one source magnet comprises translations and rotations.
 - 7. The method according to claim 5 wherein the at least one source magnet is moved in such a way as to maintain a substantially constant magnetic field strength at the operating point.
 - 8. A method of turning a medical device, having a magnetically responsive element associated with its distal end, at an operating point within an operating region inside a patient's

body, from an initial direction to a desired final direction, through the movement of at least one external source magnet, the method comprising:

- moving the external source magnet to cause the distal end of the magnetic medical device to successively align with each of a plurality of intermediate directions and the desired final direction, while maintaining a substantially constant magnetic field strength.
 - 9. A method of turning a medical device, having a magnetically responsive element associated with its distal end, at an operating point within an operating region inside a patient's body from an initial direction to a desired final direction, through the movement of at least one external source magnet, the method comprising:
- identifying a series of intermediate directions between the initial direction and the desired final direction, each intermediate direction being substantially in the plane containing the initial direction and the desired final direction;
 - determining the magnetic field direction at the operating point that will cause the magnetically responsive element to align with each of series of intermediate directions and the desired final direction;

successively moving the at least one source magnet to apply the determined magnetic field directions to align the magnetic medical device with each of the series of intermediate directions and the desired final directions.

10

5

- 10. The method according to claim 9 wherein the step of successively moving the at least one source magnet to apply the determined magnetic field directions to align the magnetic medical device with each of the series of intermediate directions and the desired final directions is done to so that the magnetic field strength at the operating point remains substantially constant.
- 11. The method according to claim 9 further comprising the step of determining the required movements of the at least one source magnet before moving the at least one source magnetic, and testing the required movements by calculating the amount by which the direction of the magnet medical device would from the plane of the initial direction during the determined required movements, and identifying a different series of intermediate directions if the variation exceeds a predetermined threshold.

- 12. The method according to claim 9 wherein the step of moving the at least one source magnet comprises determining an orientation of the at least one source magnet to apply the determined field direction.
- 13. The method according to claim 12 wherein the step of determining the orientation of the at least one source magnet to apply the determined field direction employs a look-up table.
- 14. The method according to claim 12 wherein the step of determining the orientation of the at least one source magnet to apply the determined field direction employs an equation characterizing the magnetic field of the source magnet.
- 15. The method according to claim 9 wherein the movement of the magnet from one position to another position is made by taking a number of trial movements in a plurality of different directions and testing the movement.
- 16. The method according to claim 9 wherein the step of identifying the magnetic field direction that will cause the magnetic medical device to align with each of the intermediate directions and the desired final direction, takes into account the lag between the applied magnetic field and the actual orientation of magnetic medical device.
- 17. The method according to claim 16 wherein the step of identifying the magnetic field direction that will cause the magnetic medical device to align with each of the intermediate directions and the desired final direction employs an equation to determine the lag between the applied magnetic field and the actual orientation of magnetic medical device.
- 18. The method according to claim 16 wherein the step of identifying the magnetic field direction that will cause the magnetic medical device to align with each of the intermediate directions and the desired final direction employs a look-up table to determine the lag between the applied magnetic field and the actual orientation of magnetic medical device.
- 19. The method according to claim 9 wherein identifying the magnetic field direction that will orient the magnetic element to align with each of the intermediate directions and the desired final direction is determined with an appropriate over-torque.
- 20. The method according to claim 9 further comprising computing the amount by which the magnetic medical device deviates from the plane containing the initial direction and

final direction, and identifying a new series of intermediate directions if the deviation exceeds a predetermined threshold.

- 21. The method according to claim 20 wherein the step of identifying a new series of intermediate directions comprises identifying intermediate directions based upon the direction in which the deviation of the magnetic medical device from the plane of the initial direction and the desired final direction exceeds a predetermined amount.
- 22. The method according to claim 9 wherein the desired final direction and the series of intermediate directions are identified in the patient frame of reference, and translated to the frame of reference of the at least one source magnet.
- 23. The method according to claim 9 wherein there is a look-up table of prohibited movements of the at least one source magnet, and the look-up table is referenced before moving the source magnets.
- 24. The method according to claim 9 wherein several possible movements of the at least one source magnet are determined, and the actual movement selected is selected based upon minimizing the cost function for the movement of the at least one source magnet.
- 25. A method of turning a magnet element at an operating point inside the body from an initial direction to a desired final direction by moving a source magnet outside the body, the method comprising the steps of:
- determining a series of movements of the source magnet to turn the magnetic element to successively align with a series of target directions including at least one intermediate direction between the initial direction and the desired final direction, and the desired final direction, such that the direction of the magnetic element during each movement of the source magnet in the series does not deviate from the plane of the initial direction and the desired final direction by more than a predetermined amount; and

- implementing the determined movements of the source magnet in series to turn the magnetic element from the initial direction to the final direction through the at least one intermediate direction.
 - 26. The method according to claim 25 where the step of determining the series of movements comprises:

(a) selecting an initial series of target directions;

- (b) determining the magnet movements needed to apply a magnetic field to turn the magnetic element to the target directions from their respective prior directions, and testing whether such movement causes the direction of the magnetic element to deviate from the plane of the initial direction and the final desired direction by more than a predetermined amount, and if so, selecting new and/or additional intermediate directions for the series of target directions;
- (c) repeating step (b) until series of target directions and corresponding magnet movements
 have been determined that do not cause the direction of the magnetic element to deviate from the plane of the initial target direction by more than a predetermined amount.
 - 27. A method of turning a magnet element at an operating point inside a patient's body from an initial direction to a desired final direction by moving a source magnet outside the body, the method comprising the steps of:
- (a) providing means for determining and maintaining during a procedure the location and
 orientation of the magnet element relative to the location and orientation of the external source magnet;
 - (b) choosing desired field vectors in the patient frame as a series of angularly spaced vectors which lie in the plane of the initial and final vectors and entering them in a processor;
- (c) entering the position and direction of the vectors into a processor by a means of specifying
 and displaying the field and communicating with the processor;
 - (d) calculating field directions at the operating point in the reference frame of the patient by translating the desired vectors into the reference frame of the magnet;
 - (e) transforming each one of the sequence of vectors into the reference frame of the source magnet;
- 15 (f) calculating a surface of constant field strength of desired value in the magnet frame;
 - (g) locating each of the field vectors on the appropriate latitude of the surface of constant field strength corresponding to the correct transformed direction of the field vector;

- (h) for each pair of sequential vectors of the total set, calculating the minimum motion of the source magnet required to change the field direction, taking advantage of the azimuthal symmetry of the magnet field; and
 - (i) executing the desired step turns by articulating the source magnet.

- 28. The method of claim 27 in which the articulation of the source magnet uses coordinated translations and rotations to maintain a turn nearly in a plane.
- 29. The method of claim 27 in which the magnet element is attached to a medical device.
 - 30. The method of claim 29 in which the magnet element is attached to a catheter.
- 31. The method of claim 29 in which the magnet element is attached to an endoscope.
- 32. The method of claim 29 in which the magnet element is attached to an electrode.
 - 33. The method of claim 27 in which the magnet element is attached to a guide wire.
- 34. The method of claim 27 in which the desired turn of the magnet is in a body lumen in a patient.
- 35. The method of claim 27 in which the desired turn of the magnet is in body tissue in a patient.
- 36. The method of claim 27 in which exclusion zones are entered into, and remain in the processor as vectors in the patient reference frame and transformed into the magnet frame so the processor can use them in providing the proper requested turns while avoiding interferences.
- 37. The method of claim 27 in which calculations of possible vectors with a given angular resolution are made in advance and entered into lookup tables.
- 38. The method of claim 27 in which the execution of the step turns is the articulation of a single magnet.

- 39. The method of claim 27 in which the spacing of the desired intermediate vectors of a turn is checked in the processor for departure of motion from a plane in the patient frame.
- 40. The method of claim 27 in which the calculation and execution of the step turns is the articulation of at least two magnets.
- 41. The method of claim 36 in which the exclusion zone includes both the interfering objects or beams in the patient frame and those on the articulated magnet.
- 42. The method of claim 27 in which turn limitations of the source magnet, such as those from leads, are included in the turn calculations of the processor.
- 43. The method of claim 29 in which the vectors calculated for turns take into account the departure of the magnet element in the patient from a field line which is caused by stiffness of the attached medical device to the magnet element.
- 44. The method of claim 27 in which the friction of a medium in which the turn occurs is taken into account.
- 45. The method of claim 29 in which a locating system provides information about the location, orientation, and twist of the medical device to which the magnet tip is attached.
- 46. The method of claim 45 in which the measured twist of the lumen tip is used to provide a display of the internal view from the medical device lumen, corrected for that twist, to the physician.
- 47. The method of claim 29 further comprising imaging through the medical device, and providing an intuitive interface so internal viewing through the medical device can be used to navigate the magnet element.
- 48. The method of claim 47 in which the navigation interface includes the ability to rotate about the axis of the lumen for complete inspection of the lumen.
- 49. The method of claim 47 in which the navigation includes the ability to rotate about the axis of the lumen to provide treatment at a desired point on the wall of the lumen.
 - 50. The method of claim 27 in which the locating and orienting means is magnetic.

- 51. The method of claim 52 in which during articulation of a source magnet the processor uses information on the magnet element from imaging or a locator to correct for departure of the observed motion from that requested.
- 52. A method of navigating a small magnet in a patient using articulation of an external magnet source field, in which the navigation algorithm maintains the field magnitude substantially constant at the position of the small magnet during the navigation.
- 53. A method of navigating a small magnet in a patient using articulation of an external magnet source field, in which the navigation algorithm uses the symmetry of the source magnet to achieve solutions which will minimize computer memory and time.
- 54. A method of navigating a small magnet in a patient using articulation of an external magnet source field, in which the navigation algorithm uses the symmetry of the source magnet to achieve solutions which will minimize source field magnet articulation time.
- 55. A method of navigating a small magnet in a patient using articulation of an external magnet source field, in which the navigation algorithm uses corrective feedback to reduce the need for precise characterization of distances and physical parameters while maintaining safe, efficient navigation.
- 56. A method of navigating a small magnet in a patient using articulation of an external magnet source field with one translation axis and two rotation axes of the articulator.
- 57. An articulation algorithm for providing a magnetic field in any direction at any location in a patient operating region by translating a magnet along a patient body axis, and rotating the magnet.
- 58. A method of turning a medical device having a magnetically responsive element associated with its distal end, at an operating point within an operating region inside a patient's body from an arbitrary first orientation to an arbitrary second orientation, the method comprising moving at least one source magnet in one direction of translation and two directions of rotation.